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(54) **CONTROLLER BASED ON LIFESTYLE**
EVENT DETECTION

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See application file for complete search history.

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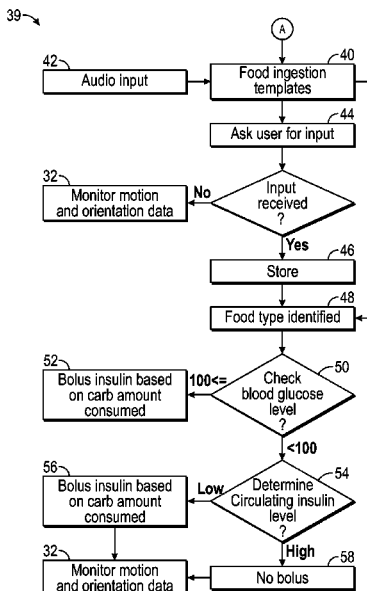
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(57) **ABSTRACT**

A controller and associated sensor system for augmenting the automatic delivery of drugs is provided. The controller and associated sensor system is based on the detection and determination of particular physical lifestyle events. As a specific example, a pump augmentation system includes a six-axis accelerometer sensor, a gyroscopic pitch sensor and a controller. The controller is configured to receive motion data from the six-axis accelerometer sensor and orientation data from the gyroscopic pitch sensor. The controller provides a pump instruction signal for changing a delivery rate of a drug to a user based on the motion data and the orientation data. When the pump is an insulin pump, the pump augmentation system is an insulin pump augmentation system and provides accurate insulin control for controlling blood glucose levels of a user.

29 Claims, 5 Drawing Sheets



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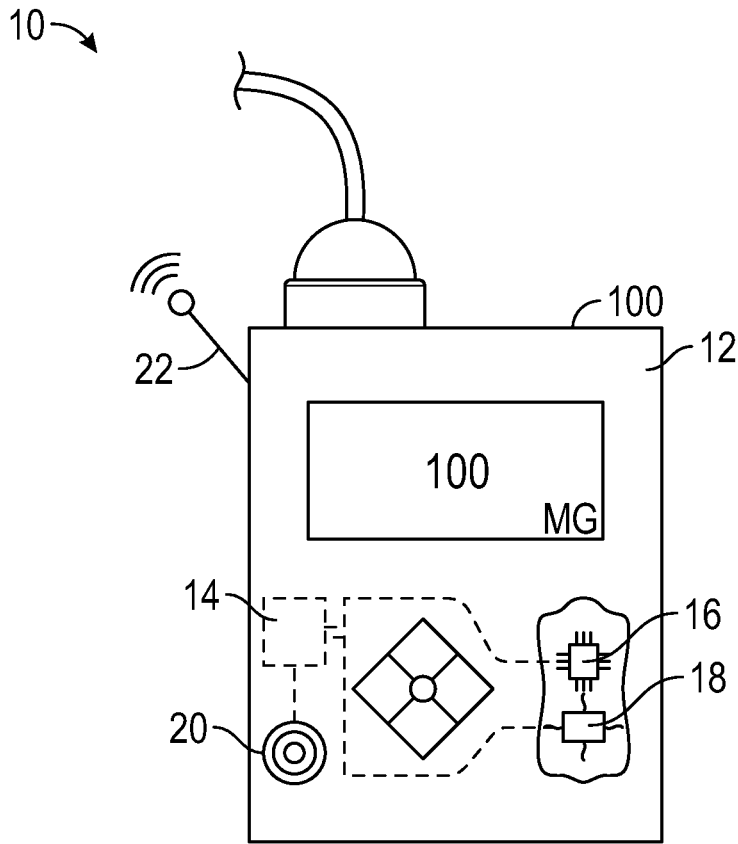


FIG. 1

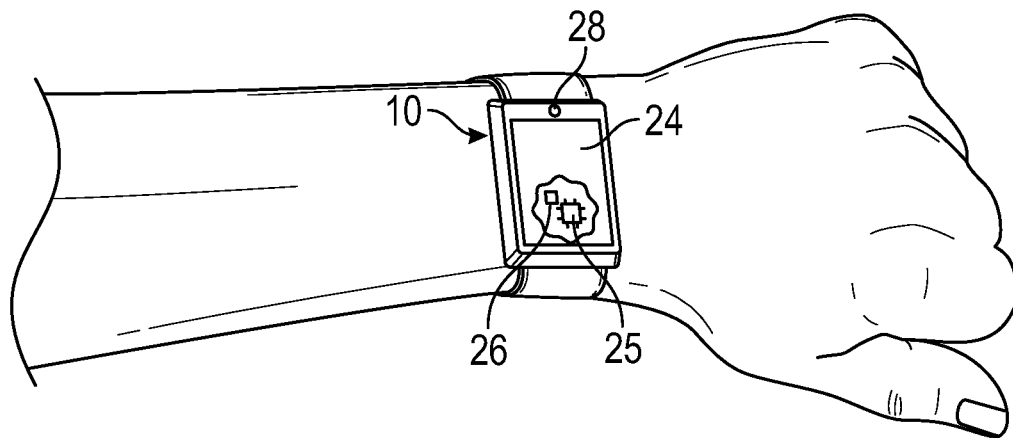


FIG. 2

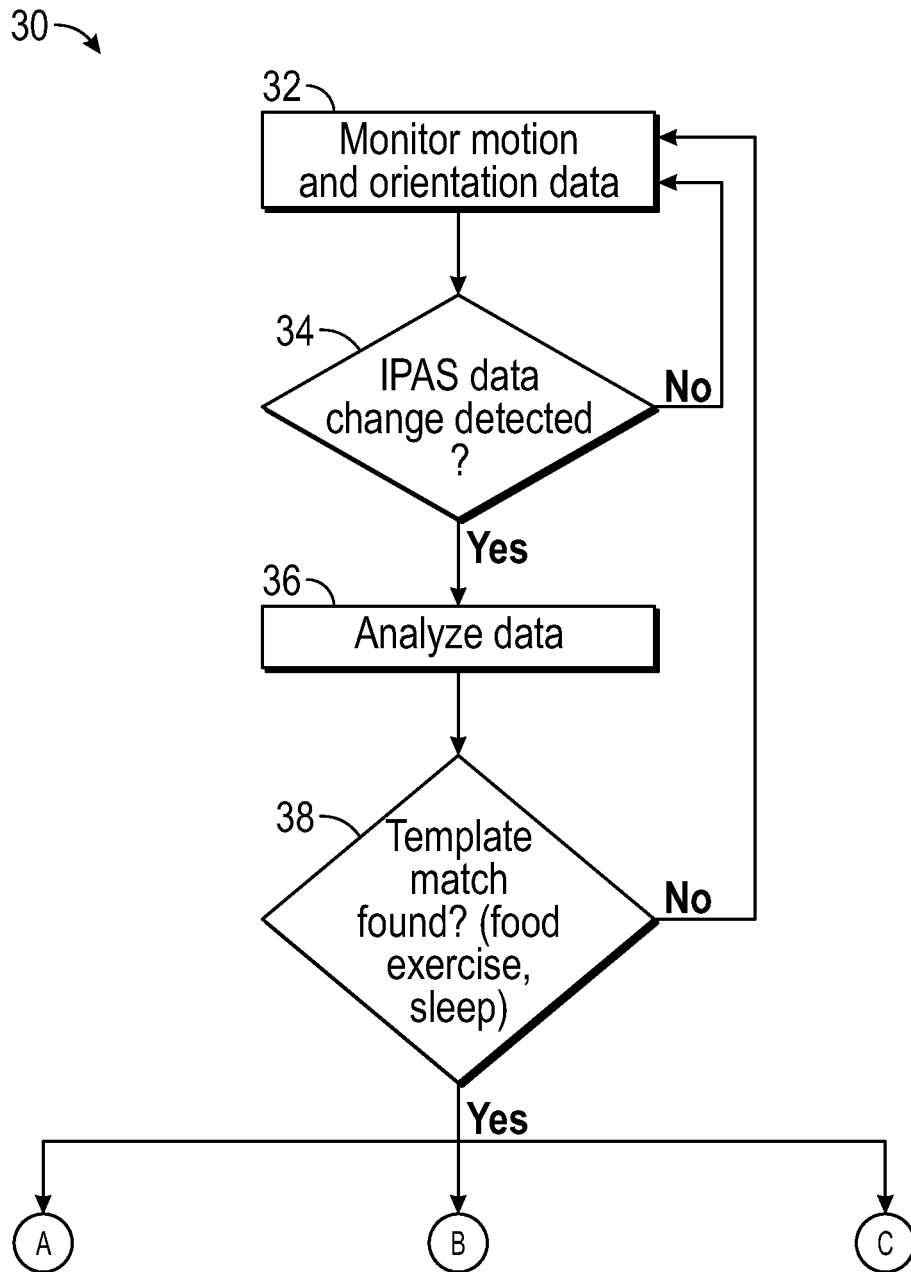


FIG. 3

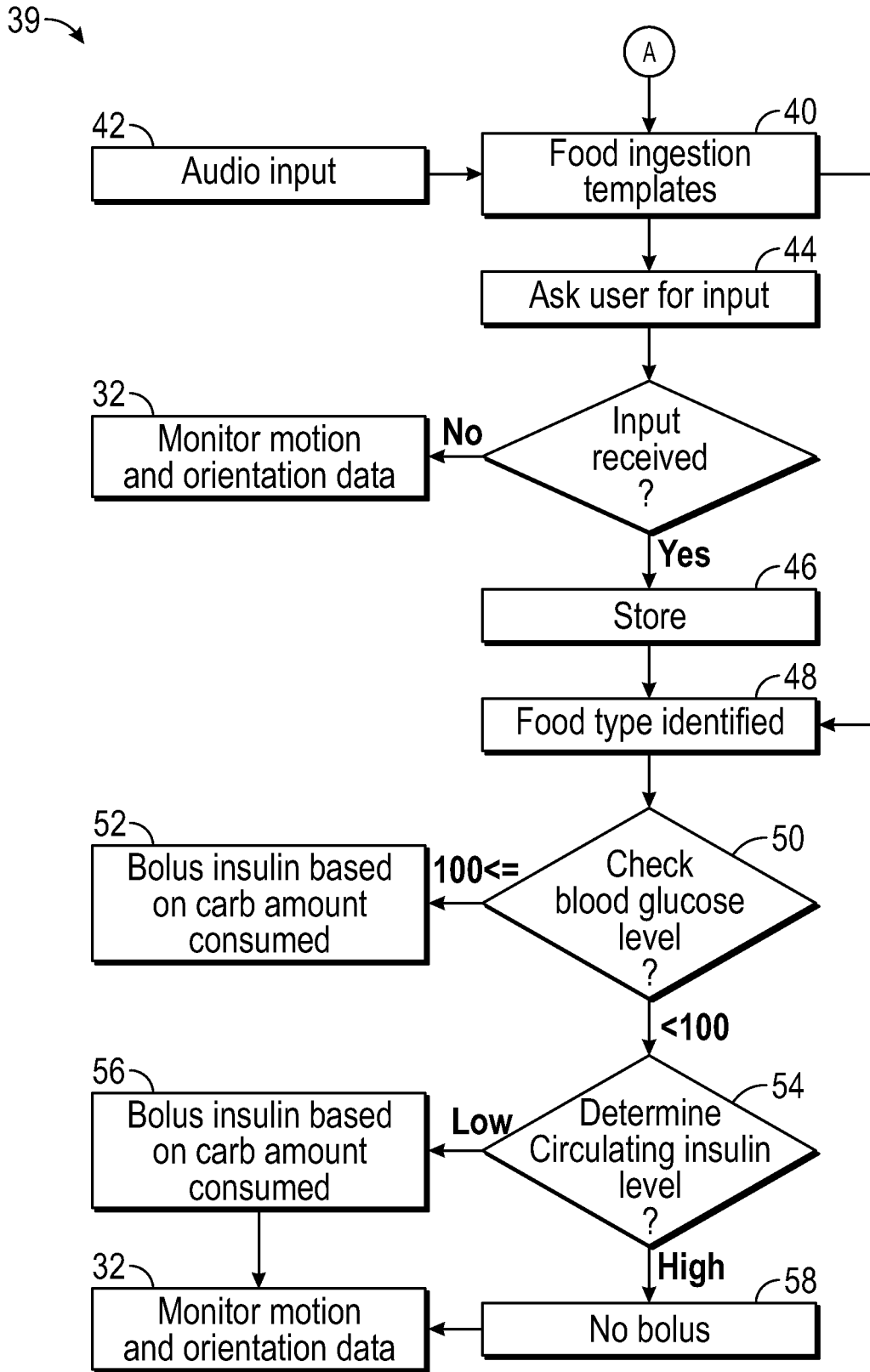


FIG. 4

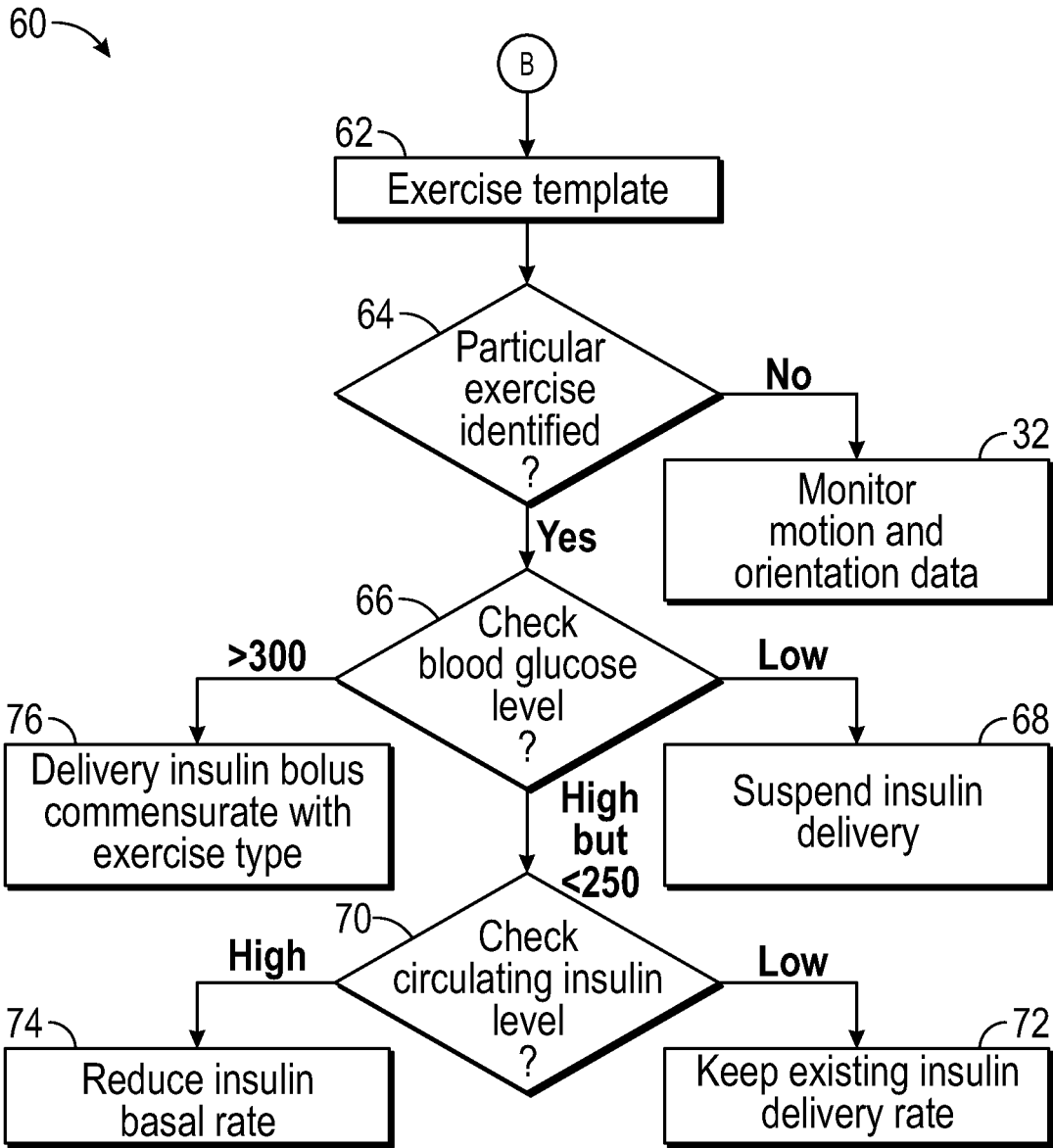


FIG. 5

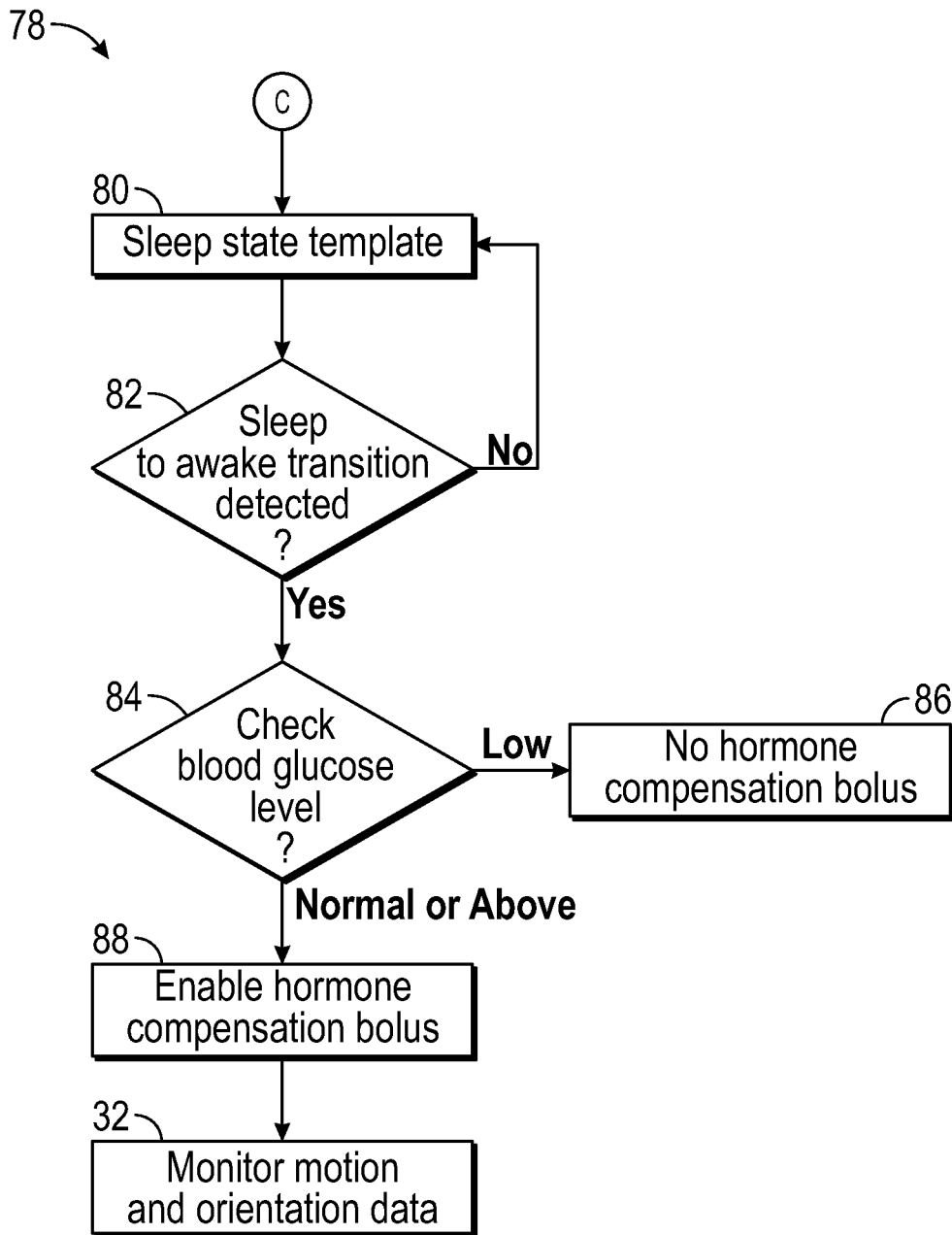


FIG. 6

1

**CONTROLLER BASED ON LIFESTYLE
EVENT DETECTION**

TECHNICAL FIELD

The present disclosure generally relates to a controller and associated sensor system based on lifestyle event detection, and more particularly relates to a controller and associated sensor system for augmenting the automatic delivery of drugs based on the detection and determination of particular lifestyle events. In one aspect, the controller and associated sensor system relates to the operation of insulin pumps, and more particularly relates to an Insulin Pump Augmentation System (IPAS) for assisting insulin pump delivery of insulin to a user based on lifestyle event detection.

BACKGROUND

Despite the progress of diabetic management via an insulin pump, even after the introduction and integration of continuous glucose monitoring with a “closed loop” approach, there still remains a disconnect between the capability of conventional insulin pump systems to satisfactorily detect and compensate for changing physiological, lifestyle, and exercise of an individual. All of these situations frequently result in unexpected raising and/or lowering of blood glucose levels, often times such that the blood glucose levels are outside of their desired, targeted or acceptable glucose ranges.

As an example, the everyday act of simply awakening for an individual triggers a release of hormones that characteristically causes a person’s blood glucose level to rise. In a non-diabetic individual, the blood glucose levels are organically adjusted so these situations go unnoticed. In a diabetic individual, however, there is no (or only a limited) physiological mechanism that recognizes and compensates for such circumstances. Currently, treatment of diabetes generally relies on an “after the fact” corrective measures to bring the changing blood glucose levels back to normal ranges.

In contrast to the need to treat rising blood glucose levels, diabetic individuals also continually face the opposite problem, even with “closed-loop” insulin pump therapy. Normal physical activity such as working, walking, or exercising can frequently bring a diabetic individual’s blood glucose level down to dangerously low levels. To complicate matters even further, in certain circumstances the same physical exertion during a period of elevated blood glucose levels can actually further increase the blood glucose levels to a dangerous degree.

At its core, the overall control problem results from the fact that insulin pumps follow a rigid, time of day based delivery process for the continuous, or basal, rate of insulin delivery, as well as only being able to react to an abnormal glucose level after a deviation has already occurred, or is in the process of taking place.

At its best, conventional insulin pumps or closed-loop insulin pumps are inherently limited to indirectly reacting to changes in interstitial fluid glucose levels, which are in of itself a delayed measure of true blood glucose levels. Present treatment methods lack the ability to dynamically and automatically proactively increase or decrease an insulin delivery rate, and therefore such methods merely treat the consequential effects of lifestyle or physiological activity.

SUMMARY

According to a first aspect, a controller based on lifestyle event detection, and more particularly a controller for aug-

2

menting the automatic delivery of drugs based on the detection and determination of particular lifestyle events may be provided.

For example, in one embodiment, an insulin pump augmentation system may include a body, an accelerometer sensor, a gyroscopic pitch sensor, and a controller. The accelerometer sensor may be arranged on the body and configured to output motion data based on detected motion. The gyroscopic pitch sensor may be arranged on the body and configured to output orientation data based on detected orientation. The controller may be in communication with the accelerometer sensor and the gyroscopic pitch sensor. Further, the controller may be configured to receive the motion data and/or the orientation data. The controller may be configured to generate a pump instruction signal based on the motion data and/or the orientation data. The pump instruction signal may include a signal to change an insulin delivery rate of an insulin pump.

The signal to change an insulin delivery rate of an insulin pump may be a signal to reduce or increase the flow of insulin, to start a flow of insulin, to stop the flow of insulin, or to deliver an insulin bolus amount.

According to another embodiment, the controller may be configured to analyze the motion data and/or the orientation data on a time weighted basis. Further, the controller may be configured to utilize a data pattern matching algorithm to provide a determination of an occurrence of a lifestyle event of a user. The data pattern matching algorithm may utilize pattern data previously entered by a user. The pump instruction signal may be based, wholly or partly, on the determined lifestyle event.

The controller may also be configured to receive circulating insulin level data indicative of a level of insulin circulating within the user. The pump instruction may be based, wholly or partly, on the circulating insulin level data.

The controller may be configured to receive blood glucose level data indicative of a level of blood glucose level within the user. The pump instruction signal may be based, wholly or partly, on the blood glucose level data.

The controller may be configured to analyze the circulating insulin level data and the blood glucose level data. The pump instruction signal may be based, wholly or partly, on the analysis of the circulating insulin level data and the blood glucose level data.

According to another aspect, the controller may be configured to analyze the circulating insulin level data and the blood glucose level data with regard to the determined lifestyle event. The pump instruction signal may be based, wholly or partly, on the analysis of the circulating insulin level data and the blood glucose level data with regard to the determined lifestyle event.

According to a further embodiment, the controller may be configured to analyze the motion data and/or the orientation data on a time weighted basis. The controller may be configured to utilize a data pattern matching algorithm to compare the motion data with one or more predetermined motion data patterns stored in the pump augmentation system. The controller may further be configured to determine at least one of a type of food being ingested by the user, a quantity of said food being ingested by the user, and a resultant carbohydrate load being ingested by the user. The controller may be configured to determine a target amount of insulin based on at least one of the determined type of food, the determined quantity of food, and the determined carbohydrate load. The pump instruction signal may be based, wholly or partly, on the determined target amount of insulin.

According to another embodiment, the controller may include a memory and be configured to store in the memory the motion data and the orientation data received by the controller during a lifestyle event of a user. Further, the motion data and orientation data may be associated with a specific type of lifestyle event of a plurality of types of lifestyle events.

According to one embodiment, the insulin pump augmentation system may be incorporated within, and operationally connected to either an internal or external insulin pump which is attached to the user.

According to one embodiment, the body of the insulin pump augmentation system may be a stand-alone wearable device configured to be worn by the user. The wearable device may be configured to be worn on a limb, such as on the arm at the wrist of the user, and is operationally connected to either an internal or external insulin pump which is attached to the user.

According to another embodiment, the insulin pump augmentation system may include a microphone configured to detect audio and to output audio data based on the detected audio. The controller may be configured to receive the audio data. The pump instruction signal may be based, wholly or partly, on the audio data received by the controller.

According to even another embodiment, the controller may include a memory and be configured to store in the memory certain previously stored audio data received by the controller during ingestion of food. The controller may also be configured to receive an identifying input from the user to define and match a particular food type of the food previously ingested and matched to the audio data received by the controller. The controller may be configured to store the audio data in association with the particular food type indicated by the input. Further, the controller may be configured to determine a particular food type based on the stored audio data.

The controller may be configured to store, into a memory, the motion data and the orientation data received by the controller during a previous ingestion of a particular type of food. In the memory, the motion data and orientation data may be associated with a particular food type of a plurality of food types.

The controller may be configured to receive a selection from the user of physical ingestion characteristics of the particular food type based on stored motion data and orientation data or other physical ingestion characteristics.

According to an embodiment, the controller may be configured to select a particular food type from a plurality of food types, stored in a memory, based on at least one of the motion data, the orientation data and the audio data. The controller may further be configured to generate the pump instruction signal based on the selection of the particular food type.

The controller may be configured to estimate a quantity of calories ingested by a user and maintain a running caloric count representative of a sum of calories ingested by the user throughout a time period. Further, the controller may be configured to generate a signal when the sum of calories ingested by the user is greater than or equal to a predetermined caloric threshold.

The controller may be configured to estimate a quantity of carbohydrates ingested by a user and maintain a running carbohydrate count representative of a sum of carbohydrates ingested by the user throughout a time period. Further, the controller may be configured to generate a signal when the sum of carbohydrates ingested by the user is greater than or equal to a predetermined carbohydrate threshold.

According to another embodiment, the insulin pump augmentation system may include an indicator emitting device configured to emit a sound(s) or vibration. The controller may be operatively connected to the indicator emitting device and configured to increase the sound level and/or vibration level and increase a duration of the sound and/or vibration when the controller determines a user is non-responsive to acknowledging the sound or vibration.

The controller may be operatively connected to a communication device, and may be configured to cause the communication device to be activated when the controller determines the user is not responding to an escalating series of alarm sounds or vibration. Optionally, when the communication device is activated, an emergency call or message may be sent that includes real-time medical information relevant to the user and/or location information.

According to another aspect, a pump augmentation system may include a body, at least a six-axis accelerometer sensor, a gyroscopic pitch sensor, and a controller. The six-axis accelerometer sensor may be arranged in or on the body and configured to output motion data based on detected motion. The gyroscopic pitch sensor may be arranged in or on the body and configured to output orientation data based on detected orientation. The controller may be operatively connected to the six-axis accelerometer and the gyroscopic pitch sensor and configured to receive the motion data and/or the orientation data. The controller may be configured to generate a pump instruction signal based on the motion data and/or the orientation data, wherein the pump instruction signal may include a signal to change a material delivery rate of a pump.

According to another aspect, a method of augmenting a pump system includes monitoring motion data and/or orientation data, and generating a pump instruction signal based on the motion data and/or the orientation data. The pump instruction signal may include a signal to change a material delivery rate of a pump. The pump system may include a device body, an accelerometer sensor arranged in or on the device body and configured to output the motion data based on detected motion, a gyroscopic pitch sensor arranged in or on the body and configured to output the orientation data based on detected orientation, and a controller connected to the accelerometer and the gyroscopic pitch sensor, the controller being configured to receive the motion data and/or the orientation data. The controller may perform the generating a pump instruction signal.

These and other objects, features and advantages of the present invention will become apparent in light of the description of embodiments and features thereof, as illustrated and enhanced by the accompanying diagrams.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an exemplary IPAS-enabled insulin pump in accordance with embodiments of the present disclosure;

FIG. 2 shows an exemplary IPAS-enabled wrist-worn device in accordance with embodiments of the present disclosure;

FIG. 3 shows an exemplary flow diagram for the operation of the IPAS of FIG. 1 in accordance with embodiments of the present disclosure;

FIG. 4 shows an exemplary flow diagram for the operation of the IPAS of FIG. 1 in accordance with embodiments of the present disclosure;

FIG. 5 shows an exemplary flow diagram for the operation of the IPAS of FIG. 1 in accordance with embodiments of the present disclosure; and

FIG. 6 shows an exemplary flow diagram for the operation of the IPAS of FIG. 1 in accordance with embodiments of the present disclosure.

DETAILED DESCRIPTION

Before various embodiments are described in further detail, it is to be understood that the present disclosure is not limited to the particular embodiments described. It will also be understood that the methods and apparatuses described herein may be adapted and modified as appropriate for the application being addressed and that the devices, systems and methods described herein may be employed in other suitable applications, and that such other additions and modifications will not depart from the scope thereof.

Although various features have been shown in different figures for simplicity, it should be readily apparent to one of skill in the art that the various features may be combined without departing from the scope of the present disclosure.

According to certain aspects, a controller associated with a Pump Augmentation System (PAS) or with an Insulin Pump Augmentation System (IPAS), in accordance with the present disclosure, provides improved pump operation or insulin pump operation control schemes and devices and systems for use with a pump or an insulin pump.

For example, the present disclosure provides an Insulin Pump Augmentation System (IPAS), which uniquely provides a closed-loop insulin pump with an understanding of various physiological and/or lifestyle activities its user is undergoing in real-time, so as to allow for dynamic proactive automatic compensation for said activities to better keep a diabetic individual's (or other individual) blood glucose level within a "desirable" target range. This proactivity is immensely important, as the mechanical insertion of insulin into a body, whether through a manual injection process or through an insulin pump, does not confer the same immediate glycemic response to a diabetic individual's glucose level, as compared to what a "normal" (non-diabetic) organic solution would provide.

There is a time lag between changes in blood glucose levels and when those changes are subsequently reflected by interstitial fluid readings, and as a result the existing "after the fact" insulin delivery reaction and correctional methods to external lifestyle factors typically result in undesirable "out of range" conditions. While insulin pumps are generally able to deliver different preset basal insulin infusion (delivery) rates based upon fixed, predetermined time schedules, these rates are not able to take into consideration the typical variations to an insulin pump user's varying schedule.

As an example, with the rise in glucose levels that diabetic individuals experience upon awakening as a result of the "Dawn Phenomenon," the best that current technology can do is to be statically programmed to allow for an increased basal insulin delivery during a specific pre-set time frame. The obvious problem with this method, however, is that unless an individual exactly conforms to the strict time schedule corresponding to the expected insulin delivery increase, this timed increased insulin delivery level will not match the actual glucose level insulin requirement, and can result in abnormally low or high blood glucose levels.

Given the reality of the numerous every-day "real-world" variations, precisely achieving both an exact time to bed, as well as an exact time of awakening in order to maintain consistent sleep durations in order to predict when a hormone release should occur is almost impossible to achieve consistently. Since present-design insulin pumps do not have the ability to recognize changes in sleep patterns (such as is

experienced with variations between weekday sleep schedules and weekend or vacation sleep schedules, etc.), there is an inherent timing issue with the present treatment methods which prevent the proper response to the "Dawn Phenomenon" blood glucose changes.

In a similar fashion, conventional insulin pumps have no way to proactively react to spontaneous physical activity, whether it is during emergency situations (such as having to run down numerous flights of during an emergency evacuation), or for pleasure (such as a spontaneous extra round of tennis or other sporting activity that was not previously envisioned), and as a result even a closed-loop insulin pump crudely attempts to reactively reduce or suspend insulin delivery after the fact in order to maintain control.

Where 'conventional' (non-PAS enabled or non-IPAS-enabled) 'smart watches' or similar devices are capable of generating reports or saving information about the total number of strides or other physical activity, these devices only display prior information such as calories burned and distances covered, and are not configured for automatic responsive action based on such information for controlling or modifying an insulin pump. In contrast, according to an aspect of the present disclosure, a controller (for example, a controller integrated into an IPAS) uses sensed data to automatically determine and provide beneficial changes to the insulin delivery rate of an insulin pump (e.g. increases and/or decreases of insulin delivery rate). The novel use of an Insulin Pump Augmentation System (IPAS), which may, for example, incorporate one or more six-axis accelerometer/gyroscopic pitch sensors (or other number of axis accelerometer(s)), and whose data output may be processed and analyzed in real-time through an artificial intelligence software program, for the first time gives a closed-loop insulin pump the ability to have physiological and/or physical situation awareness in order to better match insulin delivery levels to a body's actual insulin requirements. IPAS is also ideally suited for common problematic situations, where insulin-pump users either forget to temporarily suspend the insulin delivery of their pump beforehand and/or during exercise, and/or forget to bolus for a planned or ingested carbohydrate load. Both aforementioned situations can result in potentially serious blood-glucose excursions developing, which may be avoided through the use of IPAS according to embodiments of the present disclosure.

For the purposes of present disclosure, the term "lifestyle" includes events such as: a person's current sleep state (e.g., determining if a person is awake or sleeping); a person's current exercise or physical motion state (or movement state); a person's current food intake state (eating, chewing, drinking, etc.); and a person's real-time identification of a specific food currently being ingested as well as the total quantity of that food having been ingested. A "lifestyle" situation awareness augmentation provided to an insulin-pump by an IPAS allows a closed-loop insulin pump to monitor and automatically correct for physical exertion activity which may change a user's glucose level, a 'real-time' monitoring, identification, and insulin compensation for a range of ingested food, and the ability to monitor an individual's sleep/awake status and compensate for end-of-sleep hormone release changes to a user's blood glucose level.

According to certain aspects, a controller is associated with an Insulin Pump Augmentation System (IPAS). An IPAS can be configured in different physical embodiments, with three exemplary embodiments including:

1) IPAS components being completely integrated into the body of an IPAS-enabled insulin pump. The data from the

pump's integrated IPAS sensors being processed by an associated Artificial Intelligence sub-system within the IPAS, and the resultant guidance being provided to the insulin pump's delivery system(s) to act upon (or a controller of the insulin pump delivery system(s)).

2) The configuration of embodiment #1, further augmented by the additional use of a physically separate second six-axis accelerometer and gyroscopic pitch sensor, and a microphone that is integrated into a wrist-worn device that is placed on an insulin-pump user's arm or wrist (preferably the dominant arm or wrist), either as an IPAS-enabled smart-watch or as a proprietary IPAS wearable device. The data output from these additional sensors is transmitted to an IPAS-equipped insulin pump (e.g. through wireless communication means), where the added data stream is combined with the data supplied from the pump's integral sensor(s), with both data streams subsequently being processed by an Artificial Intelligence sub-system within the insulin pump.

3) A configuration for use with a non-IPAS enabled closed-loop insulin pump. In this configuration, all of the IPAS sensing elements as well as the IPAS data processing functions are physically integrated into the body of a "smart-watch" or other IPAS wearable device which is worn on the wrist or arm of an insulin pump user (e.g. the dominant wrist or arm). An integral six-axis accelerometer and gyroscopic pitch sensor, along with a microphone are used as input devices. In this embodiment, the IPAS-enabled arm-worn device itself calculates supplemental insulin and/or delivery modification instructions, and then wirelessly transmits said instructions to a 'conventional' insulin pump, i.e. non-IPAS equipped insulin pump, for execution. Said insulin pump would also transmit "real-time" parameters such as blood-glucose levels and circulating insulin to the IPAS device.

In a first example of what the newly-found lifestyle awareness conveys to an insulin pump, the augmented pump will now be capable of dynamically determining a sleep state or an awakened state of a user, and proactively make compensating adjustments to an insulin delivery rate commensurate with an estimated body's release of hormones upon awakening. With this new lifestyle awareness, the glucose lowering effect of insulin can now be better timed to match the escalating blood-glucose effects of a hormone release upon awakening with a commensurate insulin release upon the IPAS sensing the physically awakened state of an insulin-pump user.

In accordance with embodiments of the present disclosure, a controller associated with an IPAS may determine that an individual is in a sleeping state or non-sleeping state based on the individual's physical orientation. For example, whether said individual is physically oriented in a position characteristic of sleep along with a reduced state of motion for an extended period of time, an IPAS, through its six-axis accelerometer(s) and gyroscopic pitch sensor(s) can similarly recognize the physical positioning and a long-term lack of motion of an individual, and match this data with a stored template indicative of a sleeping state for that individual. Conversely, when the controller associated with the IPAS detects that an individual has changed from a limited motion, long duration sleeping state position to an upright position through detected multi-axis motion, then a determination of a non-sleeping state position (or awakening state or morning awakening) by the IPAS can also be made. The IPAS Artificial Intelligence subsystem can determine through an algorithm that, for example, includes a time-weighted motion analysis (to prevent short duration awakening from being incorrectly interpreted as morning awakening), as well as observing the range and speed of detected

motion, in order to filter out the typical transient movement and position shifting of an individual during various sleep phases from an actual awake state.

With the inherent ability of the controller associated with the IPAS to detect the sleeping state of a user, IPAS has the capability to not only advance or delay the pre-programmed time-based basal rates, but it can also correct and align the fixed/preset basal rates with actually observed conditions such as is encountered when sleeping or travelling between time zones. Similarly, an IPAS according to embodiments of the present disclosure can temporarily skew a current basal rate to better align with instant or predicted near future bodily insulin requirements.

An IPAS's sleep/awake determination can also provide critical user-condition determination and responses. In the instance of the controller associated with an IPAS-equipped insulin pump sensing an abnormally low (or excessively high) blood glucose reading while its user is presumed sleeping, it can both increase the volume levels of a warning alarm(s), as well as the duration of such alarms beyond its usual daytime parameters, as arousing a sleeping person experiencing low blood-glucose levels can be especially challenging. In some embodiments, in the event that an IPAS-equipped insulin pump, after the completion of an enhanced alarm sequence(s) does not sense an awakened condition, the controller associated with the IPAS is configured to presume that the user has lost consciousness (or is otherwise non-responsive) and automatically commands a nearby mobile device to place an emergency call for medical help. Simultaneously, the controller associated with the IPAS may cause an insulin pump to automatically suspend insulin delivery. In the event of a non-responsive individual along with an observed extremely low blood-glucose indication, IPAS may be configured to automatically suspend insulin delivery and/or deliver an infusion of glucose-raising medication such as Glucagon. In the case of excessively high blood glucose levels, IPAS may be configured to automatically deliver an appropriate insulin bolus to avoid or correct a ketonic situation. For example, the controller associated with the IPAS could command the nearby mobile device through Bluetooth wireless communication or the like. Even though the unconscious individual may be unable to speak, a digitized voice message would indicate to an emergency operator the nature of the medical emergency, as well as relay the location of the user through GPS or other location information technology of the mobile device should that information not be available via enhanced 911 systems. Optionally, IPAS could deliver to the emergency operator the observed blood-glucose levels for more timely situation awareness and action by first responders.

In a second example, a non-IPAS enabled insulin pump is completely ignorant as to the 'moment to moment' lifestyle activities of its user, and thus has no ability to proactively deviate from its preset delivery settings. It is well known that physical activity affects a diabetic individual's blood glucose levels, either by lowering a diabetic individual's blood-glucose level or raising it depending on what the blood glucose level is at the time of said exercise. By the use of an integrated multi-axis accelerometer and pitch sensing sensor (or separate adjunct multi-axis accelerometer and gyroscopic pitch sensors), an insulin pump is able to gain a continuous (or semi-continuous) insight into a user's exercise/physical activity, and dynamically and proactively adjust the user's insulin delivery rate accordingly, rather than attempting to reactively correct a resultant change in blood glucose level as accomplished through conventional insulin pump devices.

According to embodiments of the present disclosure, an IPAS may achieve improvements in a user's "in-range" glucose readings. Changes in exercise or physical activity can now be immediately detected (or nearly immediately) allowing for contemporaneous alteration to a user's basal insulin rate immediately (or near immediately) upon the initiation of exercise. Artificial Intelligence (A.I.) logic may be employed to both analyze a user's current blood-glucose levels as well as determine the (presently) circulating insulin levels (as provided by the insulin pump) to make appropriate insulin adjustments by the pump as needed. If the instantaneous circulating insulin level at the time of exercise is deemed adequate and the detected blood glucose level is within a 'normal' range (or within a predetermined range), then the controller associated with the IPAS may be configured to bias the insulin pump to stop or lower the insulin delivery basal rate commensurate with the sensed level and duration of exercise. If at the time of exercise commencement, the detected blood glucose level is well above normal (or is above a predetermined threshold) and/or there is a low level of circulating insulin (or is below a predetermined threshold), then the controller associated with the IPAS may be configured to cause the insulin pump to either bolus and/or increase its basal rate to compensate for the exercise so as to prevent a further increase in blood glucose levels caused by the exercise.

A determination of exercise or other strenuous activities (such as playing tennis) may be made through an A.I. motion algorithm, which may base the determination on how many active axes are reporting motion above a predetermined motion threshold level, the excursion ranges of said reporting axes, and any repeating cadence patterns (to detect running or other specific activities). The algorithm may be designed to filter out 'false' exercise reporting situations, such as when an individual is riding in a car (repeated rising up and down) so as not to confuse said vertical 'bouncing' up and down with the vertical motions one might associate with running. The motion algorithm would note that while there were vertical (and potentially other motions), the excursion distances were limited from what one would expect from exercise, with forward movements and other axis readings missing along with a very different cadence pattern.

The Insulin Pump Augmentation System (IPAS) is not limited to the lifestyle examples described herein. Conventional insulin pumps have no direct means for lifestyle awareness, and as a result of this deficiency, the pump is completely unaware of a user's food ingestion. Without a "real-time" method to sense an ingested carbohydrate load, conventional closed-loop pumps are oblivious to food being ingested, and merely indirectly and reactively sense that the user's blood glucose levels are rising toward or beyond a target range or rate before initiating corrective action. Even in the case where an insulin-pump user manually boluses insulin prior to food consumption, this action is just a guess as to how much carbohydrate may or may not subsequently get consumed.

With the present invention, an IPAS-equipped insulin pump is not only contemporaneously presented with real-time information indicative of food ingestion, but in many cases, even the precise type of food, the actual quantity of food consumed, the resultant calculated ingested carbohydrate load, the glycemic index of said food, and a compensating insulin bolus amount and release timing for that ingestion may be estimated and provided to the pump. This allows an insulin pump to immediately (or near immediately) and contemporaneously proactively match supple-

mental insulin dosages to the amount as well as type of food being consumed, as opposed to a non IPAS-equipped pump needing to reactively compensate for said food ingestion in an imperfect "after the fact" manner.

As an example, in the case of a person eating popcorn, the dominant hand (or non-dominant hand) wearing an IPAS sensor(s) repeatedly moves in a distinct pattern while taking food from a fixed "supply container" and bringing the popcorn to their mouth. By analyzing the data from one or more of the six-axis accelerometer sensors and/or one or more of the gyroscopic pitch/yaw/roll sensors during this activity, a distinctive repetition pattern allows the controller (for example, with an incorporated A.I. algorithm) to record the detected arm and hand movements, which can be accurately saved as a template representative of that particular food being ingested. The controller/A.I. system may not only analyze the repeated multi-axial positional locations, speed, and cadence of said movements, but it may also generate a digitized audio file from the wrist-mounted microphone when the wrist worn device is determined to be at the closest position to the mouth of the user. The audio file may further assist the A.I. algorithm in differentiating between, for example, a person eating popcorn and a person eating potato chips by differentiating between their distinctive chewing sounds, as well as the duration of chewing sounds.

By determining and analyzing the "linger" time that a hand is held at or near a mouth, as well as the number and type of sequential angular movements of the hand and wrists before moving away from the mouth, this allows a further quantitative determination of what has been ingested, and by supplemental simple calculation, the instantaneous carbohydrate ingestion level for each such movement cycle may be calculated, and a determination as to a compensatory insulin "bolus" is made. By infusing insulin proximate (and at the appropriate compensating level) to ingestion taking place, as tempered by the glycemic index of the identified food, a superior proactive match of insulin and carbohydrate load may be made.

The variation in types of foods is quite extensive. By having an individual "record" various foods being eaten, as well as data labeling of the recorded foods, a controller associated with an IPAS according to embodiments of the present disclosure can easily match and reference the carbohydrate value, the glycemic index, calories, etc. to precisely tailor the delivery values necessary for an insulin pump to match the insulin need and timing to compensate for a glucose level increase in the blood caused by that food when ingested.

The physical motions and cadences typically associated with eating various foods can be quite distinctive for certain foods. Examples of this include, without limitation, the eating an ear of corn, the eating an apple (with distinctive 'snap back' after each bite), the licking of an ice cream cone, the peeling and eating of a banana, etc. Because of unique physical movements while eating and/or eating sounds associated with each food, a series of specialized food templates may be generated and/or pre-stored in the controller associated with the IPAS. Additionally, manually inputting the food type into the IPAS by a user, for example by pressing a button on the wrist-worn device and speaking the name of a particular food, the carbohydrate and caloric information may be recalled (or identified) for foods that have difficulty in being automatically recognized based on a food template, and the IPAS will monitor the ingestion amount to resolve (or determine) a carbohydrate load and insulin bolus. For low-carbohydrate food such as meat, the IPAS may recog-

nize the unique motions of meat cutting before ingesting (if the user prepares the food for ingestion).

The sound characteristics of not only the actual ingestion of a beverage, but also the sounds (or lack of) created by the actual bottle or container may be especially important in identifying what the beverage (and its carbohydrate content) is. For example, disposable plastic water bottles, since they do not need to handle the pressures of carbonation, are typically constructed of much thinner plastic material than ‘soda’ bottles, and as such they produce a characteristically unique “plastic flexing/crackling” sound when handled and being consumed from. This unique plastic water bottle sound would be used by IPAS to determine that a non-caloric/zero carbohydrate ingestion was taking place. Conversely, a carbonated beverage would use a different type of bottle as well as producing different ingestion/carbonation sounds. With regard to determining whether the carbonated beverage is “diet” or regular (with their corresponding vastly different carbohydrate amounts), the IPAS algorithm merely needs to analyze the user’s blood glucose level at the time of ingestion to make a logical differentiation. Since an IPAS user is presumed to be a diabetic, then unless the user’s glucose level was low at the time of ingestion (which would make the ingestion of a “regular” soda or the like desirable in that situation), then the beverage is always assumed to be “diet”.

Every food when ingested has a unique combination of positional and rotational presentations to the mouth, a distinct biting pattern and sound, juice sucking sounds, chewing noises, hand retraction rotation and positioning, etc.

In some embodiments, the controller associated with the IPAS may not directly identify a type of food based on a pre-stored food template, but rather using a matching process wherein individual food templates are recorded and saved by the user during ingestion, with the user then manually identifying and registering each different food. Subsequent food identification may be accomplished by the IPAS automatically comparing in real-time active food ingestion with the saved digital motion and sound patterns of the saved templates. When a match is made, the carbohydrate levels, glycemic indices, caloric information, and other information is provided to the insulin delivery system for determining insulin delivery amount(s) and timing of said delivery amount(s).

The algorithm that the controller associated with the IPAS used to determine ingested food types may incorporate one or more validation methods to increase accuracy. One of these methods is to only allow food audio matching (as captured by the wrist-worn device) during periods when the IPAS motion analysis determines that a user’s hand is in a position proximate to their mouth. By the use of such ‘audio gating’, the IPAS may prevent false analysis when multiple people are eating either the same type, or other food types in close proximity to the subject IPAS. Said audio gating also inherently provides a level of privacy due to the wrist microphone being muted whenever the system does not detect a hand being raised and brought proximate to the mouth. Accordingly, the IPAS may not record audio data from the microphone when the IPAS is determined to not be at a proximate position to a mouth of the IPAS user, or disregard the recorded audio data if the IPAS is recording the audio data.

In some embodiments, the controller associated with the IPAS is configured to initially contain a number of ‘generic’ motion templates to immediately allow for recognition of awakening, running, or other activity. The IPAS is configured to not only allow a user to generate and replace said

‘generic’ templates with their own custom individualized templates to further increase both event recognition and accuracy, but also to supplement the range of stored templates. The custom personalized templates may also replace the generic motion templates or be used in addition thereto for recognition of awakening, running, or other activity.

Another benefit of a controller associated with an IPAS according to embodiments of the present disclosure comes into play during episodes of hypoglycemia. In some circumstances, individuals typically over-compensate their carbohydrate ingestion to treat the immediate symptoms of hypoglycemia. In some embodiments, the IPAS is configured to monitor an instant blood-glucose level, the amount of circulating insulin, as well as the amount of carbohydrate being ingested. The controller associated with the IPAS may be configured to provide the user with an ‘overshoot’ protection alert to guard against excessive carbohydrate ingestion subsequently resulting in hyperglycemia. By the IPAS comparing said ingestion against both the instant glucose level as well as the amount of circulating insulin, it can calculate (or determine) the appropriate amount of carbohydrate needed to normalize the user’s blood-glucose level by monitoring the instant carbohydrate ingestion and sound an alert at a point of over-compensation.

In some embodiments, the controller may be associated with a Pump Augmented System (PAS). The PAS may also be used for delivery of other infusible medications or other infusible materials, such as, for example and without limitation, medications for treating Parkinson’s disease. In this usage example, infused medication delivery time(s) and amount(s) can be matched with an instant need, as determined, for example, by an increased tremor level which a PAS would detect.

For the purposes of the present disclosure, while the primary disclosed application is for the augmentation of an insulin pump, the same or similar hardware configuration, with minor software modification, may also be used for other purposes. In a further embodiment of the controller, the automatic food ingestion sensing may also be used as an ‘ingestion’ caloric monitor as opposed to current devices that only report calories that were ‘burned’, rather than consumed. In some embodiments, a controller configured for caloric ingestion monitoring may optionally be configured to provide tactile or visual alarms or other guidance notification once a target caloric ingestion has been achieved or failed to be achieved by a certain time of day.

The present disclosure provides a controller associated with a system for sensing and determining “lifestyle” activities.

According to certain specific embodiments, an Insulin Pump Augmentation System (IPAS) for sensing and determining “lifestyle” activities of an insulin pump user is provided. As shown in FIG. 1, the Insulin Pump Augmentation System 10 in accordance with embodiments of the present disclosure is integrated into, and/or operatively in communication with an insulin pump 100 having a pump body 12. The IPAS 10 includes a controller 14, an accelerometer sensor 16, a gyroscopic pitch sensor 18, an indicator emitting device 20 and a transmitter 22. The accelerometer sensor may be a multi-axis accelerometer sensor, for example, a six-axis accelerometer sensor.

The controller 14 is operatively connected to the six-axis accelerometer sensor 16, the gyroscopic pitch sensor 18, the indicator emitting device 20 and the transmitter 22. While the controller 14 is shown as being physically connected to the six-axis accelerometer sensor 16, the gyroscopic pitch sensor 18, the indicator emitting device 20 and the trans-

13

mitter 22, the controller 14 may be “connected” to these elements through wireless communication methods and connections.

The six-axis accelerometer sensor 16 is configured to detect motion (or movement) and output motion data (or movement data). The controller 14 is configured to receive and/or record or store the motion data from the six-axis accelerometer sensor 16. The gyroscopic pitch sensor 18 is configured to detect orientation and output orientation data. The controller 14 is configured to receive and/or record the orientation data from the gyroscopic pitch sensor 18. The indicator emitting device 20 is configured to emit one or more sounds (for example, an alarm sound) at various sound levels and/or to display one or more visual indicators (for example, a flashing light). The controller 14 is operatively connected to the indicator emitting device 20. The transmitter 22 is configured to communication with one or more communication devices.

The controller 14 is configured to communicate with the insulin pump 100 and receive various insulin pump 100 data. For example, and without limitation, the controller 14 may receive circulating insulin level data of a user of the insulin pump 100, a reported blood glucose level data of the user of the insulin pump 100 and/or a current or scheduled insulin delivery rate data of the insulin pump 100. The controller 14 is operatively connected with a host insulin pump 100. The controller 14 is also operatively connected to the transmitter 22 to cause the transmitter 22 to trigger an automatic emergency call or message if one or more predetermined criteria is satisfied based on the motion data, orientation data, audio data, circulating insulin level data, reported blood glucose level data and/or current or scheduled insulin delivery rate data.

As shown in FIG. 2, the IPAS 10 is further integrated into, and/or operatively in communication with a wearable device 24. In this embodiment, the wearable device 24 is a wrist worn device. The IPAS 10 includes a six-axis accelerometer sensor 25 and gyroscopic pitch sensor 26 located in the wearable device 24. The IPAS 10 further contains a microphone 28. The microphone 28 is configured to detect audio and output audio data. The controller 14 is configured to receive the audio data from the microphone 28 and/or the wearable device 24 includes an additional controller(s) which is configured to distribute the motion data, orientation data and/or audio data to the controller 14. It should be readily understood that the microphone 28 may be arranged in other positions of the wearable device 24 and/or there be additional microphones.

In some embodiments, the controller 14 is arranged in or on the wearable device 24. In some embodiments the controller 14 is arranged in or on the insulin pump 100 as shown in FIG. 1, and a second controller is arranged in or on the wearable device 24. The second controller being configured to communicate with the first controller 14 and/or a dedicated controller of the insulin pump 100.

Referring to FIG. 3, a flow diagram 30 shows an exemplary method of operation of the IPAS 10 of FIG. 1 in accordance with embodiments of the present disclosure. At block 32, the controller 14 monitors for motion data received from one or more of the six-axis accelerometer sensors 16, 25 and for orientation data from one or more of the gyroscopic pitch sensors 18, 26. At block 34, the controller 14 determines if the motion data and/or orientation data has changed. If the controller 14 determines that there is no change in the motion data and/or orientation data, then the controller 14 returns to block 32 for monitoring. If the controller 14 determines there is a change in the motion data

14

and/or orientation data, the controller 14 proceeds to block 36 where the change in motion data and orientation data is analyzed by the controller 14. The controller 14 proceeds to block 38 where the controller 14 compares the motion data and orientation data, which may be time-weighted, for similarities with a profile template stored in the IPAS 10. If the controller 14 determines that the motion data and/or orientation data is not similar to a stored profile template, the controller 14 returns to block 32 for monitoring. If the controller 14 determines that the motion data and/or orientation data is similar to a stored template, the controller 14 determines that the motion and orientation detected is associated with the ingestion of food and proceeds to the identified profile template method.

Referring to FIG. 4, a flow diagram 39 shows an exemplary profile template method of operation of the IPAS 10 of FIG. 1 when the motion data and/or orientation data is determined as being similar to a food ingestion profile at block 38 (FIG. 3) in accordance with embodiments of the present disclosure. The controller 14 proceeds to block 40, where the controller 14 optionally receives audio input 42 from the microphone 28 (FIG. 2). The controller 14 compares the motion data, orientation data and/or audio data corresponding to the time period determined to be contemporaneous with ingestion of food for a similarity with one or more stored food ingestion templates. If the controller 14 determines that the data is similar to a stored food ingestion template, the controller proceeds to block 48, which is discussed in greater detail later herein. If the controller 14 determines that the data is not similar to a stored food ingestion template, the controller proceeds to block 44 and requests user input for food type of food being ingested. If no user input is received, the controller 14 returns to block 32 for monitoring. If user input is received, the controller 14 proceeds to block 46 and stores the motion data, orientation data and/or audio data as corresponding to a new food ingestion template of the input provided. The new food ingestion template is stored (e.g. in a memory associated with the controller) for future food ingestion template comparisons at block 40. Then the controller 14 proceeds to block 48.

At block 48, the controller 14 determines a particular food type identified as being indicative of the food being ingested by the user. The controller 14 proceeds to block 50 where the controller 14 checks for a reported blood glucose level of the user (e.g. by querying the insulin pump 100). If the reported blood glucose level is greater than or equal to a predetermined threshold (e.g. 100 mg/dl), then the controller 14 generates a pump instruction signal at block 52 causing the insulin pump 100 to bolus insulin to the user based on the amount of carbohydrate load ingested (or consumed) as determined by the controller 14, thereby changing the current or scheduled insulin delivery rate of the insulin pump 100. If the reported blood glucose level is less than a predetermined threshold (e.g. 100 mg/dl), then at block 54 the controller 14 checks a circulating insulin level within the user (e.g. by querying the insulin pump 100). If the circulating insulin level is below a predetermined threshold, at block 56 the controller 14 generates a pump instruction signal to bolus insulin to the user based on the amount of carbohydrate load ingested (or consumed) as determined by the controller 14. If the circulating insulin level is above a predetermined threshold, then at block 58, the controller 14 does not generate a pump instruction signal or generates a pump instruction signal that reduces the insulin delivery rate from the current or scheduled insulin delivery rate. Then the controller 14 returns to block 32 for monitoring.

15

Advantageously, the controller **14** being configured to request and receive input from a user at blocks **44**, **46** allows the controller **14** to repeatedly learn the physical characteristics and/or mannerisms unique to the user. The stored patterns are individualized to the user allowing the controller **14** to identify food templates (or other templates) more accurately. The controller **14** may be configured to store any number of templates input by the user giving the controller **14** the ability to store virtually infinite patterns unique to the user. The ability to store patterns unique to the user advantageously allows for the controller **14** to “learn” the user tendencies (or previously entered pattern data) that correspond to a food template (or other template). For example, a user may tend to generate one or more unique motions, orientations or sounds when engaging in a physical lifestyle event that the controller **14** can identify as a particular template once stored. Thus, when the user again engages in that lifestyle event, such as eating potato chips in a particular physical manner, the controller **14** is configured to identify the lifestyle event and generate a pump instruction signal accordingly as disclosed herein.

Referring to FIG. 5, a flow diagram **60** shows an exemplary method of operation of the IPAS **10** of FIG. 1 when the motion and/or orientation data is determined as being similar to an exercise profile at block **38** (FIG. 3) in accordance with embodiments of the present disclosure. At block **62**, the controller **14** compares the motion data and/or orientation data for similarity with a particular exercise profile. At block **64**, if the controller **14** determines that the motion data and/or orientation data does not correspond to a particular exercise profile, then the controller **14** returns to block **32** monitoring. If the controller **14** determines the data does correspond to a particular exercise profile, the controller **14** proceeds to block **66** where the controller **14** checks for a reported blood glucose level. If the reported blood glucose level is below a first threshold, the controller **14** proceeds to block **68** and generates a pump instruction signal instructing the insulin pump **100** to suspend insulin delivery or decrease insulin delivery. If the reported blood glucose level is above the first threshold but below a second threshold (e.g. 250 mg/dl), the controller **14** proceeds to block **70** and checks a circulating insulin level within the user. If the circulating insulin level is below a first insulin threshold, the controller **14** proceeds to block **72** and maintains the existing insulin delivery rate (or at least does not cause the insulin delivery rate to change significantly). If the circulating insulin level is above a second insulin threshold, the controller proceeds to block **74** and reduces the insulin basal rate. Referring back to block **66**, if the blood glucose level is greater than a third threshold, the controller **14** proceeds to block **76** and determines an increase in an insulin delivery rate and/or an insulin bolus commensurate with the particular exercise profile, the controller **14** generates a pump instruction signal to cause the insulin pump **100** to deliver the determined commensurate insulin rate or bolus.

Similar to the method discussed above in connection with FIG. 4, the controller **14** may be configured to request that the user enter an exercise template to be stored as corresponding to a recorded exercise profile. In some embodiments, the controller **14** does not need to request that the user enter an exercise or food template. The user can enter the corresponding template even when not requested by the controller **14**. The entered template is stored with recorded data from the IPAS **10**. In some embodiments the recorded data stored as the template corresponds to the data recorded during a predetermined amount of time before the entering of the template by the user, for example and without

16

limitation, one minute, two minutes or three minutes. In some embodiments, the user can choose which recorded data is associated with the entered template. For example, the user can choose the amount of time prior to the entering of the template, or the user can choose a period of recorded data that occurred earlier in the day, e.g. if the user played tennis from 1:00 PM to 2:00 PM, later that day at 6:00 PM when the user is not playing tennis, the user could choose the time playing tennis as being stored as the tennis exercise profile or template.

Referring to FIG. 6, a flow diagram **78** shows an exemplary method of operation of the IPAS **10** of FIG. 1 when the motion and/or orientation data is determined as being similar to a sleep profile at block **38** (FIG. 3) in accordance with embodiments of the present disclosure. At block **80**, the controller **14** determines a sleep state is detected. The controller **14** proceeds to block **82**, where the controller **14** continues to monitor the motion data and/or orientation data for a determination of a sleep to awake transition, which may be based on a time-weighted evaluation of the data. If no sleep to awake transition is detected, the controller returns to block **80** to check the data is similar to a sleep profile and, if in the sleep state, returns to block **82** for determining if a sleep to awake transition has occurred. If the controller **14**, determines that a sleep to awake transition has occurred (e.g. by the motion data indicating that the user is moving or walking, or the orientation data indicating that the orientation the IPAS **10** has changed), then the controller **14** proceeds to block **84** to check for a reported blood glucose level of the user. If the reported blood glucose level is below a first threshold, the controller **14** proceeds to block **86** where the controller **14** determines that no insulin bolus is necessary to compensate for hormone release associated with a transition to an awakened state as discussed herein. If the reported blood glucose level is above a second threshold, the controller **14** proceeds to block **88** where the controller **14** determines an increase in an insulin delivery rate and/or an insulin bolus to compensate for the user hormone release, then the controller **14** generates a pump instruction signal to cause the insulin pump **100** to release the appropriate insulin at the appropriate delivery rate. Then the controller **14** returns to block **32** for monitoring.

In some embodiments, an IPAS **10** is located entirely in or on an insulin pump **100** (e.g. FIG. 1). In some embodiments, an IPAS **10** is located in or on an insulin pump **100** and in or on a wearable device(s) **24** (e.g. FIGS. 1 and 2) and, as disclosed herein, the IPAS **10** elements in the wearable device **24** are configured to communicate and work with the IPAS **10** elements in the insulin pump **100**. In some embodiments, an IPAS **10** is located entirely in or on a wearable device **24** (e.g. FIG. 2) and is configured to communicate and work with a non-integrated IPAS insulin pump (i.e. does not have any IPAS functionality by itself), where the IPAS **10** in the wearable device **24** supplements or overrides at least some control of the non-integrated IPAS insulin pump functions so that the insulin pump operates like an integrated IPAS insulin pump. In some embodiments, a user might wear one or more wearable devices containing IPAS **10** elements, for example and without limitation, a wearable device on each wrist of the user.

Advantageously, IPAS enabled pumps are configured to provide advantages over non-IPAS enabled pumps. For example, without an IPAS providing an insulin pump a real-time indication of a user’s sleep status, a conventional insulin pump may generate unnecessary alarms without regard to context. As an example, some insulin pumps may keep track of the amount of remaining insulin in its reser-

voir, and at various insulin remaining levels the pump may sound an alarm indicating the situation. As a result of this, insulin pump users are often awoken to take certain actions such as to change reservoirs even though the situation is not yet critical and such actions are ill-advised to be done when just woken up in the middle of the night. In some embodiments, an IPAS enabled insulin pump may determine whether a user is sleeping, and, if an alarm is determined as being merely advisory rather than time or situation-critical, the IPAS enabled insulin pump may delay such alarms and/or notifications until the user is awake and/or until the status of the alarm becomes time-critical.

The foregoing description of embodiments of the present disclosure has been presented for the purpose of illustration and description. It is not intended to be exhaustive or to limit the invention to the form disclosed. Obvious modifications and variations are possible in light of the above disclosure and should be considered to be within the scope and spirit of the present disclosure. The embodiments described were chosen to best illustrate the principles of the invention and practical applications thereof to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as suited to the particular use contemplated.

What is claimed is:

1. An insulin pump augmentation system comprising:
a device body;

an accelerometer sensor arranged in or on the device body and configured to output motion data based on detected motion;

a gyroscopic pitch sensor arranged in or on the device body and configured to output orientation data based on detected orientation; and

a controller in communication with the accelerometer sensor and the gyroscopic pitch sensor, the controller configured to receive the motion data and/or the orientation data during a first ingestion of food and during a second ingestion of food;

wherein the controller is configured to determine positional locations of the device body, speed of the device body, linger times of the device body, and/or cadence of movement of the device body that occur during the first ingestion of food and during the second ingestion of food based on the motion data and/or the orientation data;

wherein the controller includes a memory and is configured to store in the memory the motion data and the orientation data received by the controller during the first ingestion of food, such that the motion data and/or the orientation data received during the first ingestion of food are associated with a particular food type of a plurality of food types based on a manual user identification;

wherein the controller is configured to associate the motion data and/or the orientation data monitored during the second ingestion of food with the particular food type of the plurality of food types based on one or more of: the determined positional locations of the device body, the speed of the device body, the linger times of the device body, and the cadence of the device body that occurred during the second ingestion of food being determined to be a match to one or more of: the determined positional locations of the device body, the speed of the device body, the linger times of the device body, and the cadence of the device body that occurred during the first ingestion of food;

wherein the controller is configured to generate an estimated ingested carbohydrate load and a glycemic index of food ingested during the second ingestion of food based on the motion data and the particular food type associated with the motion data, the orientation data and the particular food type associated with the orientation data, and/or the motion data, the orientation data and the particular food type associated with the motion data and the orientation data; and

wherein the controller is configured to generate a pump instruction signal based on the estimated ingested carbohydrate load and the estimated glycemic index, the pump instruction signal including an instruction to change or suspend an insulin delivery rate of an insulin pump and an instruction for when to make the change or suspension in the insulin delivery rate.

2. The insulin pump augmentation system according to claim 1, wherein the controller is configured to analyze the motion data and/or the orientation data on a time weighted basis and configured to utilize a data pattern matching algorithm for previously entered pattern data to provide a determination of an occurrence of a lifestyle event of a user, and wherein the pump instruction signal is further based on the determined lifestyle event.

3. The insulin pump augmentation system according to claim 2, wherein the controller is configured to receive circulating insulin level data indicative of a level of insulin circulating within the user, and wherein the pump instruction signal is further based on the circulating insulin level data.

4. The insulin pump augmentation system according to claim 2, wherein the controller is configured to receive blood glucose level data indicative of a level of blood glucose level within the user, and wherein the pump instruction signal is further based on the blood glucose level data.

5. The insulin pump augmentation system according to claim 2, wherein the controller is configured to receive circulating insulin level data indicative of a level of insulin circulating within the user and to receive blood glucose level data indicative of a level of blood glucose level within the user, and wherein the controller is further configured to analyze the circulating insulin level data and the blood glucose level data, and wherein the pump instruction signal is further based on the analysis of the circulating insulin level data and the blood glucose level data.

6. The insulin pump augmentation system according to claim 5, wherein the controller is configured to analyze the circulating insulin level data and the blood glucose level data with regard to the determined lifestyle event, and wherein the pump instruction signal is further based on the analysis of the circulating insulin level data and the blood glucose level data with regard to the determined lifestyle event.

7. The insulin pump augmentation system according to claim 1, wherein the controller is configured to analyze the motion data and/or the orientation data on a time weighted basis and configured to utilize a data pattern matching algorithm to compare the motion data with one or more predetermined motion data patterns wherein the controller is configured to determine at least one of a type of food being ingested by the user, a quantity of said food being ingested by the user, and a carbohydrate load being ingested by the user, wherein the controller is configured to determine a target amount of insulin based on at least one of the determined type of food, the determined quantity of food, and the determined carbohydrate load, and wherein the pump instruction signal by the controller is further based on the determined target amount of insulin.

19

8. The insulin pump augmentation system according to claim 1, wherein the controller is configured to analyze the motion data and/or the orientation data on a time weighted basis and configured to utilize a data pattern matching algorithm to provide a determination of an occurrence of a lifestyle event.

9. The insulin pump augmentation system according to claim 2, wherein the instruction to change the insulin delivery rate of the insulin pump is a signal to deliver an insulin bolus amount.

10. The insulin pump augmentation system according to claim 1, wherein the controller is configured to store in the memory the motion data and the orientation data received by the controller during a lifestyle event of a user, such that the motion data and orientation data are associated with a specific type of lifestyle event of a plurality of types of lifestyle events.

11. The insulin pump augmentation system according to claim 10, wherein the plurality of types of lifestyle events comprises eating, sleeping, awakening from a sleep state, and exercising.

12. The insulin pump augmentation system according to claim 10, wherein the device body is a wearable device configured to be worn by the user.

13. The insulin pump augmentation system according to claim 12, wherein the wearable device is configured to be worn on a limb of the user.

14. The insulin pump augmentation system according to claim 12, wherein the wearable device is configured to be worn on a wrist of the user, the insulin pump augmentation system further comprising a microphone configured to detect audio and to output audio data based on the detected audio, wherein the controller is configured to receive the output audio data, and wherein the pump instruction signal is further based on the received output audio data.

15. The insulin pump augmentation system according to claim 14, wherein the controller is configured to store in the memory the received audio data received by the controller during ingestion of food, wherein the controller is configured to receive an input from the user identifying a particular food type of the food ingested when the received audio data is received by the controller, and wherein the controller is configured to store the received audio data and match the carbohydrate content in association with the particular food type indicated by the input.

16. The insulin pump augmentation system according to claim 15, wherein the controller is configured to determine a particular food type based on the stored received audio data.

17. The insulin pump augmentation system according to claim 1, wherein the accelerometer sensor is, at a minimum, a six-axis accelerometer providing X/Y/Z orientation data, as well as Pitch/Roll/Yaw axes movement.

18. The insulin pump augmentation system according to claim 1, wherein the controller is configured to match the particular food type from the plurality of food types stored in the memory during ingestion of a second food based on at least one of the motion data, the orientation data and an audio data, and wherein the controller is further configured to generate the pump instruction signal based on the particular food type matched during the ingestion of the second food.

19. The insulin pump augmentation system according to claim 1, wherein the controller is configured to estimate a quantity of calories ingested by a user and maintain a running caloric count representative of a sum of calories ingested by the user throughout a time period.

20

20. The insulin pump augmentation system according to claim 1, wherein the controller is configured to estimate a quantity of carbohydrates ingested by a user and maintain a running carbohydrate count representative of a cumulative sum of carbohydrates ingested by the user throughout a time period.

21. The insulin pump augmentation system according to claim 19, wherein the controller is configured to generate a signal when the sum of calories ingested by the user is greater than or equal to a predetermined caloric threshold.

22. The insulin pump augmentation system according to claim 20, wherein the controller is configured to generate a signal when the sum of carbohydrates ingested by the user is greater than or equal to a predetermined carbohydrate threshold.

23. The insulin pump augmentation system according to claim 22, wherein a communication device generates an emergency call or message that includes medical information relevant to the user and/or location information.

24. The insulin pump augmentation system according to claim 1, further comprising an indicator emitting device configured to emit a sound or generate vibratory motion, wherein the controller is operatively connected to the indicator emitting device, wherein the controller is configured to increase the sound level and/or vibration level and/or increase a duration of the sound or vibration when the controller determines a user is non-responsive to the sound.

25. The insulin pump augmentation system according to claim 1, wherein the controller is operatively connected to a communication device, and wherein the controller is configured to cause the communication device to be activated when the controller determines the user is not responding to an escalating series of sounds or vibratory motions.

26. A pump augmentation system comprising:

a device body;
an accelerometer sensor arranged in or on the device body and configured to output motion data based on detected motion;

a gyroscopic pitch sensor arranged in or on the device body and configured to output orientation data based on detected orientation; and

a controller connected to the accelerometer and the gyroscopic pitch sensor, the controller being configured to receive the motion data and/or the orientation data during a first ingestion of food and during a second ingestion of food;

wherein the controller is configured to determine positional locations of the device body, speed of the device body, linger times of the device body, and/or cadence of movement of the device body based on the motion data and/or the orientation data that occur during the first ingestion of food and during the second ingestion of food;

wherein the controller includes a memory and is configured to store in the memory the motion data and the orientation data received by the controller during the first ingestion of food, such that the motion data and/or the orientation data received during the first ingestion of food are associated with a particular food type of a plurality of food types based on a manual user identification;

wherein the controller is configured to associate the motion data and/or the orientation data monitored during the second ingestion of food with the particular food type of the plurality of food types based on one or more of: the determined positional locations of the device body, the speed of the device body, the linger

21

times of the device body, and the cadence of the device body that occurred during the second ingestion of food being determined to be a match to one or more of: the determined positional locations of the device body, the speed of the device body, the linger times of the device body, and the cadence of the device body that occurred during the first ingestion of food;

wherein the controller is configured to generate an estimated ingested carbohydrate load and a glycemic index of food ingested during the second ingestion of food based on the motion data and the particular food type associated with the motion data, the orientation data and the particular food type associated with the orientation data, and/or the motion data, the orientation data and the particular food type associated with the motion data and the orientation data;

wherein the controller is configured to generate a pump instruction signal based on the estimated ingested carbohydrate load and the estimated glycemic index, the instruction signal including an instruction to change or suspend a material delivery rate of a pump and an instruction for when to make the change or suspension in material delivery rate.

27. A method of augmenting a pump system comprising: monitoring, by a controller, motion data and/or orientation data during a first ingestion of food;

determining, by the controller, positional locations of a device body, speed of the device body, linger times of the device body, and/or cadence of movement of the device body based on the motion data and/or the orientation data monitored during the first ingestion of food;

associating, by the controller, the motion data and/or the orientation data that occurred during the first ingestion of food with a particular food type of a plurality of food types based on a manual user identification;

monitoring, by the controller, motion data and/or orientation data during a second ingestion of food;

determining, by the controller, positional locations of the device body, speed of the device body, linger times of the device body, and/or cadence of movement of the device body based on the motion data and/or the orientation data monitored during the second ingestion of food;

associating, by the controller, the motion data and/or the orientation data monitored during the second ingestion of food with the particular food type of the plurality of food types based on one or more of: the determined positional locations of the device body, the speed of the device body, the linger times of the device body, and the cadence of the device body that occurred during the second ingestion of food being determined to be a match to one or more of: the determined positional locations of the device body, the speed of the device body, the linger times of the device body, and the cadence of the device body that occurred during the first ingestion of food;

generating, by the controller, an estimated ingested carbohydrate load and a glycemic index of food ingested during the second ingestion of food based on the motion data and the particular food type associated with the motion data, the orientation data and the

22

particular food type associated with the orientation data, and/or the motion data, the orientation data and the particular food type associated with the motion data and the orientation data;

generating, by the controller, a pump instruction signal based on the estimated ingested carbohydrate load and the estimated glycemic index, the pump instruction signal including an instruction to change or suspend a material delivery rate of a pump and an instruction for when to make the change or suspension in the material delivery rate.

28. The method according to claim 27, wherein the pump system comprises:

- a device body;
- an accelerometer sensor arranged in or on the device body and configured to output the motion data based on detected motion; and
- a gyroscopic pitch sensor arranged in or on the body and configured to output the orientation data based on detected orientation;

wherein the controller is connected to the accelerometer and the gyroscopic pitch sensor, the controller being configured to receive the motion data and/or the orientation data;

wherein the controller performs the step of generating a pump instruction signal; and

wherein the controller includes a memory;

wherein the method further comprises storing in the memory the motion data and the orientation data previously received by the controller during ingestion of a food, such that the motion data and/or the orientation data are associated with a particular food type of a plurality of food types.

29. The pump augmentation system according to claim 26,

- wherein the controller is configured to store in the memory the motion data and the orientation data received by the controller during a lifestyle event of a user, such that the motion data and orientation data are associated with a specific type of lifestyle event of a plurality of types of lifestyle events;
- wherein the device body is a wearable device configured to be worn by the user;
- wherein the wearable device is configured to be worn on a wrist of the user, the insulin pump augmentation system further comprising a microphone configured to detect audio and to output audio data based on the detected audio, wherein the controller is configured to receive the output audio data, and wherein the pump instruction signal is further based on the received output audio data; and
- wherein the controller is configured to store in the memory the received audio data received by the controller during ingestion of food, wherein the controller is configured to receive an input from the user identifying a particular food type of the food ingested when the received audio data is received by the controller, and wherein the controller is configured to store the received audio data in association with the particular food type indicated by the input.

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